[0089] In certain embodiments, the cartridge may be marked with identifying indicia such as cartridge parameters, cartridge type, print geometry and layout, print lot, serial number, and expiration date, either by direct printing onto the planar or by attachment of a sticker or the like, printed with identifying information. This marking allows for accurate cartridge identification and tracking based on, for example, one or two dimensional bar codes, RFID readers, or other available tracking technologies. In other embodiments, cartridge affixed RFID, or other tracking technology may be contemplated.

[0090] In certain embodiments, the cartridge may include a location for accepting sample-specific identifying information. In another embodiment, the cartridge may have a region for accepting hand-written identifying information. In another embodiment, the cartridge may have a region for applying a label, including barcodes or other sample-specific labels, for identifying the sample being processed on that cartridge.

[0091] To further improve usability, the cartridge may be further enclosed in a handling shell. The handling shell may be, for example, a low cost plastic clamshell composed of clamshell elements that snap-fit together. The clamshell may be an opaque, low cost plastic that blocks unwanted transmission of light out of the cartridge. In certain embodiments, clamshell may be color- or pattern-coded to distinguish between diagnostic and/or analyte test types.

[0092] The system presented here offers several potential technical advantages over existing technology. Most significant, in an embodiment, is the ability to perform quantitative multiplexed immunoassays on whole blood samples at the point-of-care in a cost effective manner. While some RDTs do offer a degree of multiplexing (see, for example the five band Dual-Path Platform HIV-1/2 test in development by Chem-Bio, Inc.), the system disclosed herein may readily be configured to simultaneously measure 45 different markers or more. The system described here may also provide the advantages of multiple RDTs in a single-protocol, disposable cartridge with automatic quality control features. Further, the system is capable of quantitative output more analogous to laboratory analyzers or enzyme immunoassays ("EIAs").

[0093] Referring again to FIG. **2**, in one embodiment, cartridge **110** supports a multiplexed fluorescence bioassay including a printed array of biomarkers immobilized on a waveguide contacting surface (e.g., assay region **122**) that forms a portion of cartridge **110**. Typically, prior to insertion into reader instrument **100**, the sample and other assay reagents are added to cartridge **110** according to an assay protocol. After processing, which may take minutes or even hours, the processed cartridge is then inserted into reader instrument **100**, which illuminates the waveguide at one or more different exposure times, ranging from milliseconds to seconds. Emitted fluorescence from the biomarker array is optically collected, imaged, and analyzed within a few seconds to minutes. An embedded or external microprocessor may analyze the recorded image.

[0094] Advantageously, separation of the slower cartridge processing steps from the faster reader instrument imaging steps allows for a high system throughput, since dozens to hundreds of cartridges may be prepared in batches or parallel processes by one or more technicians and, when ready, may be read relatively quickly by a single technician operating one reader instrument **100**.

[0095] Overall operation of reader instrument **100** may be controlled through a user interface **130**, which may include a touchscreen, barcode reader, operable connection to a separate computer with its own interface (not shown), and/or conventional button, toggles, switches, keyboard, voice/audio control, or other human-machine interface. In diagnostic applications, a cartridge may be processed with a sample according to clinical assay protocol specific to the cartridge being tested. The cartridge is then inserted into the reader instrument. Cartridge parameters (e.g., type, print geometry and layout, print lot, cartridge serial number, and expiration date) may be automatically read, as cartridge parameters may be encoded on the cartridge in the form of a barcode or other information indicia. The sample identifier may be input via user interface **130** into reader instrument **100**. Alternatively, the sample identifier may be read automatically. For example, a user may write information on the cartridge by hand or apply identifiers such as barcode stickers to the cartridge, which are in turn imaged or read by the reader instrument. In an embodiment, a sample record, which links cartridge parameters and sample identifier information, may be automatically generated by the reader instrument. Simultaneous cartridge and sample identifier reading in the reader instrument at the time of a measurement provides quality assurance advantages over systems that rely on manual linkage of this information.

[0096] Upon insertion, reader instrument may automatically acquire and analyze fluorescent images from imaging system **124** and cartridge **110**. This image-derived data may be analyzed to determine qualitative presence of an analyte, semi-quantitative or quantitative evaluation of analyte concentration, or even infection/disease diagnoses. Analysis results may be displayed on user interface **130**, such as a front panel display, printed, stored in memory, or transmitted to an information management system for later review.

[0097] In addition to operation simplicity, reader instrument **100** has other advantages based on its design. Generally, it is easier to manufacture and maintain devices that have few or no moving parts. Advantageously, reader instrument **100** may be constructed to have few or no moving parts. Laser illumination module **104**, and imaging system **124** may be constructed of non-moving parts that are fixed with respect to each other in operation. Shock or drop performance of reader instrument **100** is also improved by limiting the number of moving parts, making reader instrument **100** more suitable for use in field or portable applications.

[0098] Various other aspects and alternative embodiments of the described reader instrument may be better understood after consideration of the following non-limiting examples. The reagents, chemicals and other materials are presented as exemplary components or reagents, and various modifications may be made in view of the foregoing discussion within the scope of this disclosure.

Example 1

A Portable Reader Instrument

[0099] For portable or semi-portable operation, a lightweight, dimensionally small, and space efficient reader instrument is useful. The following paragraphs describe various aspects of one embodiment of such a portable reader instrument. It will be understood that this is a non-limiting example, and smaller or larger stand-alone reader instrument are contemplated, as well as reader instrument integrated as